REQUEST FOR PROPOSAL NO:	**RFP NO. NIMH-01-DS-0002**
TITLE:	**"Data Management Support and Clinical Trial Coordination for NIMH"**
OMB No:	0990-0115
ISSUED BY:	Patricia L. Gibbons Contracting Officer National Institute of Mental Health Contracts Management Branch 6001 Executive Blvd., Rm. 6107 MSC 9603 Bethesda, MD 20892-9603
DATE ISSUED:	Thursday, November 9, 2000
PROPOSAL DUE DATE AND TIME:	Wednesday, January 10, 2001, 3:30 PM EST (See ATTACHMENT 4, Packaging and Delivery of the Proposal)
PURCHASE AUTHORITY:	Public Law 95-218 as amended
SMALL BUSINESS SET-ASIDE:	Yes, 100% Set-Aside, NAICS Code 541519
JUST IN TIME:	Yes
OFFER EXPIRATION DATE:	Offers will be valid for 120 days unless a different period is specified by the Offeror

Dear Sirs:

The National Institute of Mental Health (NIMH) invites you to submit a proposal in accordance with the requirements and instructions of the above Request for Proposal (RFP). Proposals are being solicited under Small Business, 100% Set-Aside, procedures.

It is expected that one (1) cost-reimbursement, requirements task order type contract will be awarded on or before March 1, 2001, with a five (5) year base period. An option for and additional five (5) years is contemplated.

The RFP does not commit the Government to pay costs for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with any acquisition action.

SPECIAL ATTENTION SHOULD BE DIRECTED TO THE TECHNICAL PROPOSAL INSTRUCTIONS & BUSINESS PROPOSAL INSTRUCTIONS CONTAINED IN ATTACHMENT 4. Your attention is further directed to the "Proposal Intent Response Sheet" contained in ATTACHMENT 6. Please complete this form and return it to this office or notify me at the following e-mail address: pgibbons@mail.nih.gov on or before December 12, 2000. This will allow us to expedite preparations for the peer review of proposals.

IF THERE ARE ANY AMENDMENTS TO THIS SOLICITATION, THEY WILL BE AVAILABLE ON THE INTERNET (NIMH HOME PAGE) AT: http://www.nimh.nih.gov/grants/indexcon.htm. Notification of solicitation amendments to this RFP will be provided to those who submit the Proposal Intent Response Sheet. Offerors are responsible for routinely checking the NIMH website for any possible solicitation amendments that may be issued.

The documents included with this electronic RFP package are as follows:

I. Streamlined RFP
   A. Statement of Work (SOW) (ATTACHMENT 1)
   B. Deliverable and Reporting Requirements (ATTACHMENT 2)
   C. Evaluation Factors for Contract Award (ATTACHMENT 3)

II. Specific RFP Instructions and Provision (ATTACHMENT 4)

III. Proposal Intent Response Sheet (ATTACHMENT 5)

IV. Applicable RFP References (ATTACHMENT 6)
   A. Uniform Contract Format (sample contract clauses Section B-H)
   B. General Clauses and Provisions (sample contract clauses Section I-J)
   C. Forms, Formats, and ATTACHMENTS – for submissions of proposals and for information as potential contract attachments

The attachments listed above represent all the necessary information required for the submission of a proposal for this acquisition.

Your proposal must be signed by an official authorized to contractually bind your organization and must indicate that it is valid for a period of at least 120 days. One (1) original and ten (10) copies of your technical proposal and one (1) original and four (4) copies of your Business/Cost Proposal, must be received by the Contracting Officer NO LATER THAN 3:30 P.M., LOCAL PREVAILING TIME ON WEDNESDAY, JANUARY 10, 2001, at one of the following addresses:

If hand-delivered or delivery service

Contracting Officer
National Institute of Mental Health
Contracts Management Branch
6001 Executive Blvd., Rm. 6107, MSC 9603
Rockville, MD 20852-9603

If using U.S. Postal Service

Contracting Officer
National Institute of Mental Health
Contracts Management Branch
6001 Executive Blvd., Rm. 6107, MSC 9603
Bethesda, MD 20852-9603

Questions concerning any areas of uncertainty which in your opinion require clarification or correction, must be furnished in writing, (Fax or e-mail is also acceptable) to Patricia L. Gibbons, and marked "Offeror's Questions, RFP No. NIMH-01-DS-0002". Questions pertaining to the Government's requirement or proposal preparation should be referred only to Patricia L. Gibbons, Contracts Management Branch, NIMH, who may be contacted at (301) 443-2696, fax (301) 443-0501, or email pgibbons@mail.nih.gov. Collect calls will not be accepted.

ANY DISCUSSION OF THIS RFP WITH ANY INDIVIDUAL (S) OUTSIDE THE CONTRACTS MANAGEMENT BRANCH, NIMH, MAY RESULT IN DISQUALIFICATION OF THE OFFEROR AND REJECTION OF ANY PROPOSAL SUBMITTED.

Sincerely,

/s/

Patricia L. Gibbons, Contracting Officer
Contracts Management Branch, ORM
National Institute of Mental Health, NIH

ATTACHMENTS: 1 – 6

ATTACHMENT 1 [Return to Table]
RFP No. NIMH-01-DS-0002

STATEMENT OF WORK

Description/Specification/Work Statement

TITLE: Data Management Support and Clinical Trial Coordination for NIMH

I. Background Information and Objectives

A. Background Information

The NIMH is seeking general clinical coordination, data management and statistical services for multisite clinical research trials. The National Institute of Mental Health (NIMH) uses contracts to conduct numerous multisite clinical trials. Sometimes awards are made directly to clinical sites to carry out the research and a Contractor is needed to provide clinical coordination and data management support for those trials. Other times, an award is made to a Data and Clinical Coordinating Center which in turn subcontracts with clinical sites to carry out the research. In those cases, a wider range of services is needed. For example, NIMH's Child & Adolescent Treatment & Preventive Interventions Research Branch sponsors and directly funds small clinical trials under the Research Units in Pediatric Psychopharmacology (RUPP). Trials conducted under this network generally have from 100 to 140 subjects, take about three years to complete, and involve one to six sites. Another example is the follow-up study of the Multimodal Treatment Study of Children with Attention Deficit Hyperactivity Disorder (MTA). The MTA was a randomized clinical trial that compared the relative effectiveness of different treatments in a sample of 579 children with ADHD, aged 7-9 years. Seven clinical sites participated in the study that was conducted under an NIMH-sponsored cooperative agreement. Now, the long-term effects of these treatments will be assessed prospectively, using contracts awarded directly to the sites.

B. Objectives

The major objectives of this contract for each trial are, as necessary, to work with the clinical sites, the NIMH and the Statistical Investigator to accomplish the scientific goals of each multisite clinical trial in a high quality, timely and cost efficient manner.

II. SERVICES TO BE PERFORMED

A. General Requirements

1. Independently, and not as an agent of the Government, the Contractor shall furnish all necessary labor, services, equipment, materials, and supplies (except as otherwise specified herein) and perform the work set forth below.

2. All work under the contract shall be monitored by the Government Project Officer (GPO) whose position is defined in Section G, Contract Administration Data.

Specific Requirements

Work shall not commence under this contract until the Contracting Officer issues a Task Order. Each Task Order will identify which of the Tasks or parts of Tasks, identified below, the Contractor will be required to perform. The Task Order will also identify the Period of Performance for the Task, the Name of the Clinical Trial, a copy of the trial protocol, as well as any other unique information pertaining to the Task. Possible tasks the Contractor may be required to perform include the following (however, note Task XIV below):

Task I. Work Plan.

1a. Within 1 week of the issuance of a Task Order, the Contractor shall submit a specific work plan for successfully conducting the data management aspects of the project, which evidences creative data management skills to be utilized to accomplish contract requirements. The work plan shall: 1) describe an overall management plan which guarantees quality control; 2) identify hardware and software needs, if any, and evidence that the Contractor has all the necessary hardware and software to conduct the work; and 3) describe technical milestones for the performance of the entire contract which will ensure: (a) reliable data entry of all study data; (b) a central database management system to be developed, tested and operative within 24 weeks after contract award; (c) any necessary training of sites shall take place prior to the start of data collection and any necessary assistance from the Contractor shall be available as needed; (d) a data coordinating system shall be in place that permits an ongoing dialogue with the sites to ensure that information stored in the central database is accurate i.e. verified, edited, and up-to-date; and (e) the central database shall have a system in place for providing data to the statistical analysts (to be identified in the Task Order) in a timely fashion for quarterly Data and Safety Monitoring Board (DSMB) reports and/or other reports as required.

The Work Plan shall further: (1) specify a plan for having available for utilization in the study, specific software both for the sites (if remote site data entry is to be used) as well as the central database; (2) specify the language for the edit programs, which language may either be within the software system chosen for the database management system or external to it; (3) include a description of tests to be performed to demonstrate that the required system is functional; and (4) include a description of plans for backup and security of the database at all stages.

1b. For trials which require more than data management services, the draft plan shall also specify appropriate milestones, as required, for: finalization of the protocol and necessary data collection instruments; production and distribution of data collection instruments; the development of site selection criteria, solicitation, evaluation and selection of sites; preparation of consent documents, and documents necessary for other approvals and exemptions; development of a web site for the trial; conduct of data audits and/or other quality assurance activities; coordination with pharmaceutical companies who may supply the medication; performance of appropriate statistical analyses for quarterly DSMB reports and other analyses as required.

As part of this contract, the Contractor shall not purchase any hardware or software for use by the Contractor, without the express prior written approval of the Contracting Officer. The Contractor should not plan to supply hardware to the sites. Prior to obtaining any equipment with contract funds, the Contractor must provide three or more written competitive quotes with rationale to support the purchase of the equipment to the Contracting Officer for written contract approval and authorization to proceed. The invoice requesting payment for the equipment must be supported by form HHS 565, "Report of Accountable Personal Property." This report must also be submitted annually by October 31 of each year and include all property acquired by the Contractor with contract funds. A copy of the form HHS565 may be accessed off the internet at URL: http://forms.psc.gov/forms/HHS/hhs.html.

2. Within two weeks of the task order award date, the Contractor's Project Director/Manager and other key project staff shall meet with the GPO and other designated NIMH staff to discuss the draft work plan.

3. Approximately two weeks after receipt of the draft work plan, the GPO will provide written comments to the Contractor, and the Contractor shall meet with the GPO as necessary to resolve any remaining issues.

4. Within 4 weeks of receipt of the GPO's comments, the Contractor shall revise the work plan and submit it to the GPO.

The work plan shall be revised as needed throughout the contract period.

Task II. Meet or Teleconference with site investigators and NIMH staff to identify data and variables for specific study design.

1. Shortly after award of a site contract, site investigators and NIMH staff will hold a series of meetings about the protocol and study procedures, including sample design and data collection instruments. The Contractor's Project Director/Manager shall participate in these calls. It is expected that during the first year of a trial, there will be weekly teleconferences between the GPO and/or designated NIMH staff, Contractor's Project Director/Manager, the study's Executive Secretary or other designated leader, and the Site Principal Investigators/Site Coordinators/Statistical Investigators. Each teleconference will last approximately 60 minutes.

2. Throughout the course of the trial, it is anticipated that there will be every other week teleconferences among the participating sites, NIMH, and the Contractor. The Contractor shall coordinate the data aspects of the trial and, along with the GPO, take responsibility for leading the calls and keeping a record of decisions made and disseminate (via e-mail) decisions made to appropriate Clinical Site Staff and GPO. The Contractor shall be available to the sites to resolve questions they may have concerning data collection, data definitions, assessment timing, etc.

Task III. Establish a uniform format and methodology for the multiple sites to collect data.

1. It is expected that instruments will be identified for data collection within 12 weeks after award of the trial. The Contractor shall develop printed paper coding forms within one week

after each instrument is decided so that final data packets can be distributed within 16 weeks of the award of the trial. Uniform data collection forms will be used across all sites. The Contractor shall be responsible for obtaining copyright permissions where necessary.

2. The Contractor shall provide the necessary number of copies of each form, distributed among the participating sites. Printing of the forms will be the responsibility of the Contractor. Delivery may occur in phases or all at once, with the constraint that the Contractor shall deliver the forms to each site by the time that data collection commences.

3. The Contractor shall establish procedures to safeguard the confidentiality of any clinical information. Refer to the Clauses entitled "Privacy Act" and "Confidentiality of Information" located in Section H of the contract, for details regarding the safeguarding of confidential information.

Based on the cost effectiveness, cost efficiency and in consultation with the NIMH GPO, the Contractor may perform either Tasks IV or V or a combination of Tasks IV and V as follows. Regardless of whether the Contractor performs Task IV or Task V, the Contractor shall provide evidence that the method of data entry chosen is the most effective method, considering both cost and accuracy.

Task IV. Remote Site Data Entry.

If remote site data entry is used, the Contractor shall:

1. Incorporate identifiers, data, and variables for specific study design into the remote site entry system.

2. Data screens shall be coordinated with the data forms and shall emphasize ease of use both for raters and for data entry personnel. Based on comments by the GPO, the Contractor shall make any needed changes in the screens.

3. Establish a method for the accurate and secure transmission of data from sites to the central system (e.g., web-based transmission, modem transfer, etc.).

4. Within 24 weeks after award of the trial, the Contractor shall prepare a manual that describes the use of the remote site data entry system and provide training in the use of the system to personnel at the sites. Training may be in-person or otherwise, as directed by the GPO.

5. Provide for professional data entry personnel at clinical sites.

Task V. Transmitting data entry forms via mail or other process.

If data collection forms are mailed to the data management center, or transmitted by some other process, the Contractor shall:

1. Specify plans for managing receipt of data.

2. Ensure the safety of transmission including plans for the production of paper instruments that will allow copies to be kept at the site, safe and timely mailing of paper forms to the Data Center, procedures at the Data Center for receiving, logging, tracking, entering and storing paper forms.

3. If another process other than transmitting the data collection forms via the mail is employed, the Contractor must specify how this will be accomplished, including issues mentioned in Item 2 above.

Task VI. Develop and test central database management system, including subject treatment assignment system, query/resolution system, data inventories, and clinical site payment system.

1. Within 12 weeks after trial award, the Contractor shall have developed and implemented subject identification and treatment randomization schemas.

2. Within 24 weeks of award of trial, the Contractor shall finalize the central database system, finalize the data query system (edits and resolution) and test that the system is robust and the query system is accurate. The system shall provide an appropriate audit trail of all data entry as well as data modifications regardless of where the entry or modifications take place. The proposal should include a description of how the Contractor plans to demonstrate that the system works, e.g., can incorporate new data and accurately identify data problems. The data editing routine shall include, at a minimum, programs to read each data record entered or received at the central system and to check for out-of-range and missing data items, as well as check for inconsistent or illogical responses both within forms and among forms for the same individuals/families. Messages from editing routines shall be clear and specific enough to be answered by data and rater personnel at the sites with little or no need for further clarification.

3. The method of interacting with the sites for resolution and correction of queries (e.g., missing, inconsistent or invalid data entries) shall be in place within 24 weeks of the trial award and a description of this should be included in the proposal. At a minimum, where identified errors are retrievable and/or reparable, site personnel shall provide missing or replacement values for identified problems or acknowledge that existing problems must stand (e.g., accept a missing item as missing). The Contractor should have a system for differentiating acceptable records from those awaiting edit and/or resolution. The Contractor should have a system for re-editing records after corrections have been applied to ensure that new inconsistencies do not arise from corrections. The database management system shall provide the capability of admitting good "clean" records to be merged into the continually expanding main file while holding "bad" records until they are either corrected or determined to be acceptable. In addition, the system should include a process for the detection of records with duplicate identifiers.

4. Within 24 weeks of award of trial, the Contractor shall develop and implement a plan for ensuring the accuracy of data entry, e.g., double keying or other plan. The proposal should include a description of how the Contractor plans to do this.

5. Within 24 weeks after trial award, the Contractor shall also have in place a subject and data tracking system which identifies completed, due and overdue visits as well as entered data, due data and data still outstanding (overdue). Data missed (irretrievable) shall also be identified.

Task VII. Monitor the quality of data from sites.

1. Using the data inventories of accumulated and missing forms as well as visit tracking of assessments, the Contractor shall monitor the performance of the sites in terms of obtaining data from subjects, completeness of data, cleanliness of data and ability to have the data transferred to the Data Center.

2. On an ongoing basis, the Contractor shall make all attempts to rectify data problems with the sites, including notification to the GPO of sites failing to perform at the highest levels.

Task VIII. The Contractor shall maintain the entire system in good working order throughout the period of this trial.

If a remote site data entry system or some other hardware/software system is used, the Contractor shall respond to all problems reported by the sites in the operation of the system, including, but not limited to, malfunctioning software and lack of understanding on the part of site personnel as to proper operation of the system. The response will be made in a timely fashion so as to minimize any disruption in the flow of data into the system. It is anticipated that the individual sites will be responsible for repair of the hardware as that becomes necessary. A log of problems addressed and actions taken to resolve these problems shall be kept and shall be included in the progress reports.

Task IX. The Contractor shall provide the data and reports specified below to the GPO.

1. Provide a copy of the up-to-date database to the GPO and/or to the Statistical Investigator at specified points throughout the study. Depending on the assessment interval agreed upon, it is possible that a fully documented, clean, complete, up-to-date database, including scored and calculated variables, may be required for analysis after each assessment point. At the end of the trial, the Contractor shall provide to the GPO and/or the Statistical Investigator a copy of the final, clean, up-to-date database, including all variables, all patients and all assessment points and including full, clear, comprehensive documentation (see Item 3 below). The exact format of the database is not specified here, but must be easily uploaded to be used with software such as SAS and/or other readily available statistical software systems.

2. Within 4 weeks from the contract award date, and monthly thereafter, the Contractor shall submit a letter-type progress report. The report shall provide the following information, separately for each trial: (l) detail activities which involve expenditures and obligations with current month totals and cumulated totals from the trial award date; (2) problems encountered and how they were (or will be) resolved; (3) planned activities for the upcoming reporting period. After fieldwork is under way, the report shall include a summary of the flow and quality of data coming from each site. The report shall identify problems that develop concerning quality control and/or data flow from sites and shall recommend procedures to solve problems(s). The Contractor may choose to provide the information on assessments obtained, data flow, etc.

in electronic format and/or via tables or other reports that the Contractor maintains on a regular basis on a secure, password protected Website.

3. Create a data codebook documenting the description of variables contained in the database. At a minimum, the data codebook shall include: variable name, item number, longer description of variable, specifications of variable type (e.g. numeric, alpha, length, etc.), data collection instrument from which variable is collected; range and definitions of values or anchor points; description (as above) of any derived or computed variables.

4. Provide copies of all editing programs or algorithms used at the data management center.

5. Provide a description of administrative system established for rectifying the data errors from and at the sites (Task VI.2).

6. Provide sample packets of forms and instructional materials used in this project.

7. Provide data and status of the study reports to the DSMB on a quarterly (every three months) basis, as required.

8. Provide data summaries or statistical reports for special meetings such as meetings of the scientific advisors.

Task X. Carry out Start-Up/Preliminary Phase Clinical Coordinating Center Tasks, as necessary.

1. Develop criteria for participating sites, solicit for, evaluate and select sites for participation.

2. Work with the NIMH, where appropriate, to develop consent documents and to prepare packages for obtaining NIH Clinical Exemption, HHS Certificates of Confidentiality, HHS Project Assurances, FDA Investigational New Drug exemptions, etc.

3. Coordinate with pharmaceutical companies who may supply the medications for a trial and coordinate/arrange for packaging, shipping, tracking, monitoring and accountability of medication.

4. Coordinate Institutional Review Board/human subjects approvals at each participating site.

5. Develop and maintain a manual of operations for the sites participating in the trial as well as Standard Operating Procedures for the Coordinating Center itself.

6. Coordinate rater training and reliability assessments across participating sites.

7. Coordinate recruitment planning by the participating sites.

Task XI. Conduct quality assurance site visits, as necessary.

The Contractor shall conduct site visits to each of the clinical sites at least once a year to ensure

compliance and constancy across sites and assist in resolving recruiting problems should they occur. Prepare a report of each site monitoring visit within two weeks of the site visit and submit to the GPO.

Task XII. Perform descriptive and appropriate statistical analyses during each study, in coordination with the Statistical Investigator.

The Contractor, working in conjunction with the Clinical Sites, the GPO, scientific experts, and consultants, shall expeditiously prepare reports on the study results for publication in peer-reviewed scientific journals. Publication activities shall be coordinated by an ad hoc constituted Publication Committee, which shall include representatives of the Clinical Sites and the GPO. No publications or release of data shall take place without the approval of the Publication Committee and the GPO until all the primary papers have been published. After all the primary papers have been published, a copy of the data base will be made available directly to each Clinical Site Principal Investigator involved in the study and other reports for publication may be produced without the approval of the GPO, but with appropriate acknowledgement of the contract as the source of the data. (Refer to HHSAR Clause 352.270-6 "Publication and Publicity" and the Clause entitled "Publication and Publicity" located in Section H of the contract).

Task XIII. Develop and maintain appropriate web site.

The Contractor shall work with the NIMH Communications team to design, establish, implement, and maintain a clinical trial web site specifically geared to the particular study and input and maintain clinical trial specific information in http://www.clinicaltrials.gov

Task XIV. Ongoing Clinical Trial Coordinating Center include, but are not limited to the following.

1. Provide psychopharmacologic expertise to ensure medical monitoring of the trial, ensure the safety of the patients, and compliance of the sites to the protocol.

2. Provide an administrative infrastructure that can manage numerous subcontractors, can maintain fiscal control, and can easily adapt to adding and terminating subcontractors for recruitment inadequacies.

3. Ensure that regular contacts take place among clinical sites such as weekly calls and training meetings.

4. Identify obstacles and resolutions to the timely completion of the work and bring them to the attention of the GPO.

5. Coordinate the preparation of the final protocol and be responsible for updating amendments as needed.

6. Develop and implement methods for rater training and reliability assessments for ensuring rater reliability both within and between clinical sites over the course of the study.

7. Assist the GPO in scheduling, preparing and, attending steering committee meeting's, and in preparing and distributing minutes of each meeting and any other correspondence necessary.

Task XV. Options

The Contractor may be required to perform, as identified in the Task Order, other duties directly related to the performance of the contract, up to an amount not to exceed 5% of the total negotiated value (of Tasks I – XIV) of the contract.

ATTACHMENT 2 [Return to Table]
RFP No. NIMH-01-DS-0002

DELIVERABLES, REPORTING REQUIREMENTS/PERFORMANCE

1. PERFORMANCE PERIOD

Performance of this contract shall begin on (effective date of contract) and shall not extend beyond the estimated completion date, unless the contract is extended by modification to the contract.

2. PERFORMANCE

Satisfactory performance of the final contract shall be deemed to occur upon delivery and acceptance by the Contacting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule. The following are typical reports that are likely to be required of any task orders that are issued under the contract. When a Task Order is issued, the Contractor shall prepare and submit the reports in the manner stated in the Task Order Request. For specific clinical studies, special reports may be required, at the request of the Project Officer.

A. Technical Reports

The Contractor shall prepare and submit the following reports for each task order in the manner stated below:

1. Semi-Annual Technical Progress Reports - by the fifteenth working day of the month following the end of each six-month period of the task order, the Contractor shall submit three (3) copies of a semi-annual Technical Progress Report, comprising two (2) copies to the Project Officer and one (1) copy to the Contracting Officer. Such reports shall include the following specific information:

a. A cover page that lists the contract number and contract title, task order number and title, the period of performance being reported, the contractor's names and address, the author(s), and the date of submission;
b. SECTION I - An introduction covering the purpose and scope of the task order effort;
c. SECTION II - A description of overall progress for each task order or other logical segment of work on which effort was expended during the report period. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project. Other information contained shall include graphs and tables of subject recruitment and retention, status of subject follow-up, laboratory and serological testing status, summary of all adverse events reported;
d. SECTION III - Substantive performance; a description of current technical performance and any problems encountered and/or which may exist along with proposed corrective

action. Each clinical study should be reported separately according to the number assigned by the Project Officer. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and if behind planned progress what corrective steps are planned.

e. An anticipated work plan for the following six months.
f. Preprints, reprints, and abstracts related to the task order shall be submitted along with the report.

Semi-annual Technical Progress Reports are not due for periods in which an annual or final report is due.

2. Annual Technical Progress Reports - On the anniversary date of the task order, the Contractor shall submit six (3) copies of an Annual Technical Progress Report, as above, comprising two (2) copies to the Project Officer and one (1) copy to the Contracting Officer. Such reports shall detail, document, and summarize the results of the entire task order work for the period covered. These reports shall be in sufficient detail to explain comprehensively the results achieved. Also to be included in the report is a summary of work proposed for the next reporting period. An annual report will not be required for the
period when the final report is due. Preprints and reprints of papers and abstracts not submitted in the semi-annual report shall be submitted.

3. Final Report - The contractor shall submit three (3) copies of the final report documents, two (2) copies to the Project Officer and one (1) copy to the Contracting Officer, which will summarize the results of the entire task order work for the complete performance period. This report will be in sufficient detail to explain comprehensively the results achieved and will be submitted no later than the completion date of the Task Order. The final report shall contain:

a. Title Page as described above in paragraph A.1a.
b. Introduction covering the purpose and scope of the task order effort.
c. Description of the overall progress, plus a separate description of each protocol and subcontract, protocol employed and its modifications and performance on the task order during the period of performance. Descriptions will include pertinent data in tables or graphs as appropriate to present significant results achieved, conclusions resulting from analysis, and a scientific evaluation of the data accrued under the task order.
d. Copies of any abstracts, manuscripts, and publications related to the task order.

4. If the Contractor becomes unable to deliver the reports or other deliverables here specified within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons therefore at the address given below.

Deliverable	**No. of Copies**	**Addressee**
Semi-annual	2	Government Project Officer 6001 Executive Blvd., Rm. Bethesda, Maryland 20892
Annual	2	Same as P.O. above
Final	2	Same as P.O. above
Semi-annual	1	Contracting Officer 6001 Executive Blvd., Rm. 6107 Bethesda, Maryland 20892
Annual	1	Same as C.O. above
Final	1	Same as C.O. above

3. FAR CLAUSES REGARDING PERFORMANCE

In addition, the following FAR Clauses apply to this solicitation and are incorporated by reference with the same force and effect as is set forth in the full text.

FAR CLAUSE	TITLE AND DATE
1. 52.242.15	Stop Work Order (August 1989), Alternate I (April 1984)
2. 52.246-8	Inspection of Research and Development – Cost Reimbursement (1984)

ATTACHMENT 3 [Return to Table]
RFP No. NIMH-01-DS-0002

EVALUATION FACTORS FOR CONTRACT AWARD

1. GENERAL

The evaluation will be based on the demonstrated capabilities of the offerors in relation to the needs of the project as set forth in the RFP. The merit of each proposal will be evaluated carefully, based on responsiveness to the RFP and thoroughness and feasibility of the technical approach taken. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

Failure to provide the information required to evaluate the proposal may result in rejection of that proposal without further consideration. Proposals which merely offer to conduct a project in accordance with the requirements of the Government's scope of work will be considered non-responsive to this request and will not be considered further. Offerors must submit an explanation of the technical approach and a detailed description of the tasks to be performed to achieve the project objectives.

2. RELATIVE IMPORTANCE OF TECHNICAL AND COST FACTORS

Award will be made based on technical and cost factors. Paramount consideration shall be given to the evaluation of the technical proposals, but not to the exclusion of cost considerations. While high competency is sought, capabilities that exceed those needed for successful performance of the contract work/statement are not requested. In the event that the technical evaluation reveals that multiple Offerors are approximately equal in technical ability, then the estimated cost of performance will become paramount. Proposals are intended to be evaluated and award made after discussions with Offerors, but an award may be made without discussions with Offerors.

3. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. Proposals submitted in response to this RFP will be evaluated based on the following factors, which are listed and weighted in order of their relative importance.

	CRITERIA	WEIGHT
A.	**TECHNICAL APPROACH**	**60**

The proposal should demonstrate:

1. Soundness and practicality of the technical approach for responding to the objectives as stated in the Statement of Work, with adequate justification and substantiation for the recommended methods; adequacy of the administrative framework, with lines of authority and responsibility clearly shown, and adequacy of the work plan; and demonstration of Offeror's understanding of the scope and purpose of this work, including discussion of potential difficulties which may arise in the performance of this work. The evaluation will assess:

    a. Technical approach for establishing and operating a reliable, well-monitored, efficient, secure and responsive study and data management system, for procedures to handle data typically from multicenter clinical studies and for interfacing with NIMH and study sites. (20 pts)

    b. Technical approach for providing statistical scientific leadership and advice in planning assigned collaborative research efforts involving NIMH-sponsored investigators such as the MTA study and for conducting and interpreting statistical analyses. (20 pts)

    c. Technical approach for coordinating studies: including organizational logistical aspects, monitoring clincial sites, distributing study drug, training and interactions including cultivation of commitment of participating clinical units and productive interaction among them. (20 pts)

B. PERSONNEL & MANAGEMENT PLAN 25

The Offeror shall demonstrate that they have staff with appropriate training, expertise, experience, and availability to plan and implement this project as described in the Statement of Work. The proposal should demonstrate:

1. Appropriate training, expertise, experience, availability and levels of utilization of contractor/subcontractor staff required to plan and implement this project as described in the Statement of Work. The evaluation will assess:

        a. Roles, responsibilities and lines of authority of Clinical Trial/Data Coordinating Center staff in these activities.

        b. Documentation to endorse and explain previous efforts that reflect length and variety or experience in similar tasks and clearly demonstrate specific accomplishments.

2. Experience of Principal Investigator in managing and directing statistical and data management support for multicenter clinical trials as well as overall administrative ability to run multisite Clinical Trial Coordinating Activities.

3. Composite expertise of professional personnel in trials of mental health or treatments for mental health disorders, and particularly multicenter study management and statistical analyses, including evidence of interactive collaboration with clinicians.

4. Documented expertise of computing staff in computer methods for data management and statistical analysis of clinical data, documented expertise in electronic connections to remote systems and proficiency with software and operating system(s) proposed to accomplish the Statement of Work, including some proficiency with standard commercial software as necessary for consulting.

C. FACILITIES AND RESOURCES 15

Adequacy and availability of the facilities and resources necessary for conducting study coordination and data management and analysis, including computers, phone lines and other equipment, in order to successfully implement the requirements of the proposed work.

4. EVALUATION OF OPTIONS

It is anticipated that any contract awarded from this solicitation will contain option provisions(s) and period(s). In accordance with FAR Clause 52.217-5, Evaluation of Options (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise any option.

5. PAST PERFORMANCE

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any oferor whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offerors, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offerors' likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror at it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of

controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

ATTACHMENT 4 [Return to Table]
RFP No. NIMH-01-DS-0002

INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

A. JUST IN TIME

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals. Certain documents will no longer be required to be submitted with initial proposals, but will be requested at a later stage in the discussion process. Specifically, the travel policy, the annual financial statement, the total compensation plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

Travel Policy: The offeror's(and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their Final Proposal Revision (FPR).

Annual Report: The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a copy of their most recent annual report as a part of their final FPR.

Total Compensation Plan: The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a total compensation plans as a part of their FPR.

B. NOTICE OF SMALL BUSINESS SET-ASIDE

(1) **General:** Bids or proposals under this procurement are solicited only from small business concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer (CO), alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.

(2) **Definitions:** The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the criteria set forth in the regulations of the Small Business Administration (13 CFR 121.3-8). In addition to meeting these criteria, a manufacturer or a regular dealer submitting bids or proposals in his own name must agree to furnish in the

performance of the contract end items manufactured or produced in the United States, its territories and possessions, Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia, by small business concerns. Provided that this additional requirement does not apply in connection with construction or service contracts.

C. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications, specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATIONS, FAR Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is 541519.

2. The small business size standard is $ 15 Million.

D. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that requirements task order type contract will be awarded from this solicitation and that the award will be made on or about March 1, 2001.

E. COMMITMENT OF PUBLIC FUNDS

The CO is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

F. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the CO cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

G. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

H. COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

The relative importance of the evaluation factors is specified in ATTACHMENT 3 of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

I. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

J. SERVICE OF PROTEST (AUGUST 1996) – FAR 52.233-2

Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the CO (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

If hand-delivered or delivery service	If using U.S. Postal Service
National Institute of Mental Health Contracts Management Branch Attn: Contracting Officer 6001 Executive Boulevard Room 6107, MSC 9603 Rockville, Maryland 20852	National Institute of Mental Health Contracts Management Branch Attn: Contracting Officer 6001 Executive Boulevard, Room 6107, MSC 9603 Bethesda, Maryland 20892-9603

The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

K. SAFETY AND HEALTH (DEVIATION) PHS 352.223-70 (Aug 1997)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State and local laws and regulations applicable to the work being performed under this contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer in conjunction with the project or other appropriate officer, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" Clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply promptly with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of clause)

L. GOVERNMENT NOTICE FOR HANDLING PROPOSALS

NOTE: This Notice is for the Technical Evaluation Review Group who will be reviewing the proposals submitted in response to this RFP. THE OFFEROR SHALL PLACE A COPY OF THIS NOTICE BEHIND THE TITLE PAGE OF EACH COPY OF THE TECHNICAL PROPOSAL.

GOVERNMENT NOTICE OF HANDLING PROPOSALS

This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices which the submitter places on this proposal shall be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR paragraph 315.608-72.

(a) If authorized in agency implementing regulations, agencies may release proposals outside the Government for evaluation, consistent with the following:

(1) Decisions to release proposals outside the Government for evaluation purposes shall be made by the agency head or designee;

(2) Written agreement must be obtained from the evaluator that the information (data) contained in the proposal will be used only for evaluation purposes and will not be further disclosed;

(3) Any authorized restrictive legends placed on the proposal by the prospective Contractor or subcontractor or by the Government shall be applied to any reproduction or abstracted information made by the evaluator;

(4) Upon completing the evaluation, all copies of the proposal, as well as any abstracts thereof, shall be returned to the Government office which initially furnished them for evaluation; and

(5) All determinations to release the proposal outside the Government take into consideration requirements for avoiding organizational conflicts of interest and the competitive relationship, if any, between the prospective Contractor or subcontractor and the prospective outside evaluator.

(b) The submitter of any proposal shall be provided notice adequate to afford an opportunity to take appropriate action before release of any information (data) contained therein pursuant to a request under the Freedom of Information Act (5 U.S.C. 552); and, time permitting, the submitter should be consulted to obtain assistance in determining the eligibility of the information (data) in question as an exemption under the Act. (See also Subpart 24.2, Freedom of Information Act)

M. GENERAL INSTRUCTIONS

The following instructions will establish the acceptable minimum requirements for the format and content of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions. Also, please note that the technical proposal must be organized and presented in accordance with the "Technical Proposal Instructions " (Paragraph M. below).

(1) **Type Contract and General Clauses**

It is contemplated that a cost-reimbursement, requirements, task order type contract will be awarded. (See General Information). Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the address in the attached solicitation cover letter, and mark each package as follows: RFP No. NIMH-01-DS-0002 TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

(a) COVER SHEET

Include RFP number, title, name of organization, name of Principal Investigator, names of other offeror key personnel, name of any subcontractor(s) and their proposed Principal Investigator(s), names of any collaborators or consultants, and indicate whether the proposal is an original or a copy.

(b) TECHNICAL PROPOSAL

Format and organization of the technical proposal must follow the Table of Contents, and must include the information requested in the Technical Proposal Instructions and as otherwise specified in the APPLICABLE RFP REFERENCES (ATTACHMENT 5).

(c) BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as otherwise specified in the APPLICABLE RFP REFERENCES (ATTACHMENT 5).

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See ATTACHMENT 5)

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resource information, such as labor-hours and categories, materials, subcontracts, travel, etc, and associated cost so that the offeror's understanding of the project may be evaluated. (See ATTACHMENT 5)

However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided , that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Confidentiality of Proposals (HHSAR 352.215-12, Restriction on Disclosure and Use of Data (April 1984))**

The proposal submitted in response to this RFP may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) Officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act, and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal; the Government shall have the right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act.

The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

In addition, the offeror should mark each page of data it wishes to restrict with the following legend:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal."

NOTE: Offerors are cautioned that proposals submitted with the restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(7) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in ATTACHMENT 3, “Evaluation Factors for Contract Award”.

(8) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the CO determines that the initial prices are fair and reasonable and that discussions are not necessary.

(9) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon(as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(10) **Human Subjects**

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (SEPTEMBER 1985)

a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Protection from Research Risks (OPRR), National Institutes of Health, Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The Public Health Service will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR, (telephone: 301-496-7041), is recommended.

e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for

the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

f) It is recommended that OPRR be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(11) **Privacy Act**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and, as applicable, P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

The System of Records applicable to this requirement may be accessed at URL: http://www.nimh.nih.gov/grants/privacyact1997.pdf

(12) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract- All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct limited negotiations after Final Proposal Revisions (FPRs) in accordance with HHSAR 315.670.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NIMH reserves the right to make a single award, multiple awards, or no award at all from this RFP. In addition, the RFP may be amended or canceled as necessary to meet NIMH requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily.

(13) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research" which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), [(this was reprinted to correct typesetting errors from Federal Register dated March 9, 1994 (FR 59 11146-11151)], and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Refer to ATTACHMENT 5 of the RFP for information on where to obtain a copy of this Guide.

Unless otherwise specified in this solicitation, the Government has determined that the work set forth herein does not involve a gender specific study or a single or limited number of minority population groups. Therefore, the NIMH believes that the inclusion of women and minority populations is appropriate for this project. (Refer to ATTACHMENT 3 of this RFP for more information about evaluation factors for award.)

The format for the Annual Technical Progress Report Format for Each Study (See ATTACHMENT 5 of this RFP) shall be used in proposal preparation.

(14) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are scientific or ethical reasons not to include them. For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational

interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. In the technical proposal, the offeror should create a section titled "Participation of Children." This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. The RFP will contain a review criterion addressing the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification of exclusion.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998, see ATTACHMENT 5 of this RFP for information on where to obtain a copy of this Guide.

(15) **Salary Rate Limitation in Fiscal Year 2000**

Offerors are advised that pursuant to P.L. 106-113, no NIH Fiscal Year 2000 (October 1, 1999 - September 30, 2000) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses). This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II*. The salary rate limitation set by P.L. 106-113 applies only to Fiscal Year 2000 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level II* annual salary rate limit also applies to individuals proposed under subcontracts. P.L. 106-113 states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level II."

***This rate may change periodically. For your information, the rate can be found at URL: http://www.opm.gov/oca/2000tbls/Execses/html/execschd.htm**

(16) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through sub grantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and(2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

(1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

(2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

(3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

(4) the Institution will otherwise comply with the regulations.

(17) **Institutional Management of Conflicting Interests**

(1) The designated official(s) must: (i) review all financial disclosures; and(ii) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

i. public disclosure of significant financial interests;
ii. monitoring of research by independent reviewers;
iii. modification of the research plan;
iv. disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
v . divestiture of significant financial interests; or
vi. severance of relationships that create actual or potential conflicts of interests.

(2) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (1) of this section, as the Institution deems appropriate.

(18) **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates the following solicitation provisions by reference with the same force and effect as if they were given in full text. Upon request, the CO will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
b. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
c. Order of Precedence - Uniform Contract Format, FAR Clause 52.215-8 (October 1997)
d. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000) FAR Clause 52.222-24, (February 1999)
e. Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data, FAR 52.215-20 (October 1997)

N. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted for each proposed objective indicating how each aspect of the objective is to be accomplished. Your technical proposal should be in as much detail as you consider necessary to fully explain your proposed technical approach and methodology. The technical proposal should reflect a clear understanding of the nature of the work being undertaken and must include information on how the project is to be organized, staffed, and managed. The Technical Proposal should be organized and presented as stated below.

1. **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a. **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the Statement of Work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the CO. Unless the RFP indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b. **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible. If the Principal Investigator proposed for this RFP is committed in excess of 100% of his/her time the proposal must include appropriate explanations.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.
-Their availability to the project and the amount of time anticipated.
-Willingness to act as a consultant.
-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications. Resumes must not exceed two pages.

c. **Facilities and Resources**

List/describe all facilities and resources available for this project, including any equipment.

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause:

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing, and sequencing) from, into and between the twentieth and twenty-first centuries and Year 1999 and Year 2000 and leap year calculations.

d. **Summary of Related Activities**

The offeror shall complete and include with the technical proposal the "Summary of Current and Proposed Activities" form, see ATTACHMENT 5, of this RFP. Include this form with the Other Considerations portion of your technical proposal.

2. **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Evaluation Factors for Contract Award (ATTACHMENT 3).

3. **Additional Technical Proposal Information**

a. Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b. The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by the initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

4. **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

(a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the Statement of Work will be accomplished within this working relationship.

(b) Unique arrangements which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

(c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

(d) Other factors you feel are important and support your proposed research.

(e) Recommendations for changing reporting requirements or other deliverables if such changes would be more compatible with the offeror's proposed schedules.

O. BUSINESS PROPOSAL INSTRUCTIONS

For proposal purposes, all offerors are required to submit a "Budget" for the following hypothetical Task Order:

Sample Clinical Trial, Randomized, Double-Blind Study of fluoxetine vs placebo in children with Generalized Anxiety Disorder (GAD).

Children, ages 8 to 17, with diagnosed GAD will be randomly assigned to receive either fluoxetine or an inactive placebo for 12 weeks. Each child will be monitored for symptoms and side effects throughout the study. Each child will have blood tests at Weeks 4, 8, and 12 to measure drug levels in the blood (plasma levels). The study will last for 12 weeks. The study will be conducted at 5 sites around the country (assume 3 East Coast sites, 1 Mid-West site, and 1 West Coast site). The study will recruit 120 subjects, approximately evenly distributed at each site.

Patients are assessed for psychiatric symptomatology, functional status and side effects. Assume that medication and matching placebo will be supplied and distributed by pharmaceutical company.

Inclusion Criteria:
-Age 8 to 17 years
-Both males and females
-Diagnosis of Generalized Anxiety Disorder

Exclusion Criteria:
-Patients with current major depression
-Patients with panic disorder
-Patients with obsessive-compulsive disorder
-Current substance abuse

1. **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2. **Cost and Pricing Data**

(a) General Instructions

(1) You must provide the following information on the first page of your pricing proposal:

(i) Solicitation, contract, and/or modification number;
(ii) Name and address of offeror, to include DUNS number;
(iii) Name and telephone number of point of contact;
(iv) Name of contract administration office (if available);
(v) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
(vi) Proposed cost; profit or fee; and total;
(vii) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
(viii) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
(ix) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the CO and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
(x) Date of submission; and
(xi) Name, title and signature of authorized representative.

(b) In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

(c) As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
(2) The nature and amount of any contingencies included in the proposed price.

(d) You must show the relationship between contract line item prices and the total contract price. You must attach cost element breakdowns for each proposed research objective, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" (see paragraph 3 below). You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

(e) When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

(f) Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

(g) If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

(h) As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

3. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

(a) Direct Labor

Provide a time-phased (e.g. monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish basis for estimates.

(b) Fringe Benefits

Show fringe benefits as a separate line item. Include the rates(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or organizational guidelines.

(c) Materials and services

Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2, below. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) Adequate Price Competition. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) All Other. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective

source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The CO may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

(d) Indirect Costs

Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

(e) Special Equipment

If direct charge, list any equipment proposed including description, price, quantify, total price, purchase of lease, and the basis for pricing.

(f) Travel

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

(g) Other Costs

List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

(h) Royalties

If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers.
(4) Patent application serial numbers, or other basis on which the royalty is payable.
(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
(6) Percentage or dollar rate of royalty per unit.
(7) Unit price of contract item.
(8) Number of units.
(9) Total dollar amount of royalties.
(10) If specifically requested by the CO, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

(i) Facilities Capital Cost of Money (Commercial Organizations, only)

When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

4. **Formats for Submission of Line Item Summaries**

A separate cost/price estimate shall be provided for each research objective that you may propose. Individual cost/price estimates shall be furnished in accordance with the detailed breakdown in the format similar to that shown on the "Business Proposal Cost Information" form, see ATTACHMENT 5 of this RFP. For each separate cost/price estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. Further, in an effort to assist the cost proposal review process, Offerors who have prepared their business proposal using the following software spreadsheet programs are requested to provide a copy of the cost proposal spreadsheet(s) on a computer disk (high density) along with the submission of your paper copies of the business proposal. IBM PC compatible software programs are: Excel; Lotus 1-2-3; and Quattro Pro.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at URL: http://rcb.nci.nih.gov/form/cpi.htm

There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or

by specific identification, to the CO or an authorized representative. As later information comes into your possession, it should be submitted promptly to the CO in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

By submitting your proposal, you grant the CO or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price. [Note to Offerors of RFPs using "JUST IN TIME" procedures: Data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) shall not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only indicate from what source the proposed costs and prices are substantiated.

5. **Total Compensation Plan - Instructions**

********* ***This document is INCLUDED in the "Just In Time" procedures.*** **********

a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors INCLUDED IN DISCUSSIONS WILL BE REQUIRED TO SUBMIT a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

6. **Total Compensation Plan - Evaluation**

a) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

7. **Qualifications of the Offeror**

a) You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

(1) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

(2) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

(3) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

(4) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

(5) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and, while not a specific weighted evaluation factor, they are inherent in one or more technical evaluation criterion. Also, they may be used to conduct a relative assessment of offerors during the source selection process if the evaluation factors for contract award, in the specific RFP so indicate.

8. **Past Performance**

(a) Offerors shall submit the following information as a part of their Business proposal.

A List of the last five (5) contracts completed during the past three (3) years and all contracts currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local Governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort.

The offeror should provide information on problems encountered on the identified contracts and the offeror's corrective actions.

(b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

9. **Property, Equipment, Facilities**

(a) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only

when approved by the CO. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes, in addition to the description and estimated cost of each item:

(1) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(2) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(b) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(c) If an offeror intends to use existing Government-owned facilities in the performance of this proposed contract, the following shall be furnished with the offer: (1) Description and value of all Government production and research property which the offeror or his/her anticipated subcontractors propose to use on a rent-free basis and the cognizant Government Contract Number; (2) Written permission of the CO having cognizance of the property for use of that property without charges; (3) Amount of use (in months) to be made of such property, and (4) Amount of rent which would otherwise be charged for such use, computed in accordance with applicable procurement regulations.

(d) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

10. **Royalties**

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

11. **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)**

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).

(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

12. **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

13. **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

Sufficient funds are not presently available to cover the total cost of the complete multiple year project described in this solicitation. However, it is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the FAR clause 52.232.22, entitled "Limitation of Funds." Under that clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover an initial period of performance. Additional funds are intended to be allotted from time to time, to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

The "Limitation of Funds" clause to be included in the resultant contract shall supersede the "Limitation of Cost" clause found in the General Clauses.

14. **Facilities Capital Cost of Money, FAR 52.215-16 (October 1997)**

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by including one of the following statements:

-The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10), or

-The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

15. **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

(a) Willingness to perform as a subcontractor for specific duties (list duties).
(b) What priority the work will be given and how it will relate to other work.
(c) The amount of time and facilities available to this project.
(d) Information on their cognizant field audit offices.
(e) How rights to publications and patents are to be handled.
(f) A complete cost proposal in the same format as the offeror's cost proposal.

16. **Representations and Certifications**

One copy of the Representations and Certifications shall be completed and signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor. http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm

ATTACHMENT 5 [Return to Table]
RFP NIMH-01-DS-0002 PROPOSAL INTENT RESPONSE SHEET

PROPOSAL INTENT RESPONSE SHEET

PLEASE REVIEW THE ATTACHED RFP. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE ON OR BEFORE **DECEMBER 12, 2000**. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION. CHECK ONLY ONE BOX.

[] DO INTEND TO SUBMIT A PROPOSAL

[] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:
_____

TYPED NAME AND TITLE:_____

INSTITUTION:_____

SIGNATURE:_____

TELEPHONE NO.:_____

EMAIL ADDRESS: _____

FAX NO. _____

DATE:_____

COLLABORATORS/CONSULTANTS - Provide name(s) and institution(s): (Continue list on additional pages if necessary)
_____
_____
_____

TO: National Institute of Mental Health
Contracts Management Branch
Attn: Patricia L. Gibbons
6001 Exec. Blvd., Rm. 6107, MSC 9603
Bethesda, MD 20892-9603
FAX (301) 443-0501

ATTACHMENT 6 [Return to Table]
RFP No. NIMH-01-DS-0002

APPLICABLE REFERENCES

A. The following general clauses and provisions are applicable to this specific RFP depending on your organizational status: Negotiated Cost-Reimbursement Research and Development Contract. The clauses are located in the file "GENERAL CLAUSES" at URL: http://rcb.nci.nih.gov/clauses/clauses.html.

B. The following items are applicable to this specific RFP and are located in the file entitled (except as noted) FORMS, FORMATS AND ATTACHMENTS at URL: http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm

SUBMIT WITH TECHNICAL PROPOSAL (with original and every copy of technical proposal)

1. Technical Proposal Cover Sheet
2. Summary of Current and Proposed Activities
3. Technical Proposal Cost Information

SUBMIT WITH BUSINESS PROPOSAL:

1. Proposal Summary and Data record, NIH-2043, with every copy of business proposal
2. Business Proposal Cost Information
3. Disclosure of Lobbying Activities, OMB SF-LLL, only one completed and signed original
4. Representations and Certifications - Negotiated Contract, only one completed and signed copy

OTHER - TO BE SUBMITTED LATER:

1. Certificate of Current Cost or Pricing Data, NIH-1397, to be submitted with FPR, if required by the CO

ANTICIPATED TO BE INCLUDED AS CONTRACT ATTACHMENTS:

1. Invoice/Financing Requests Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1
2. NIH 2706, Financial Report of Individual Project/Contract, the form with instructions
3. Procurement of Certain Equipment, NIH(RC)-7
4. NIH Women and Minority Policy
5. Protection of Human Subjects Assurance/Identification/Certification/Declaration, OF310
6. NIH Policy for the Inclusion of Children as Participants In Research Involving Human Subjects
7. Annual Technical Progress Report Format for Each Study

C. The Sample Contract Format for R&D Cost Reimbursement contracts is located in the file entitled, FORMS, FORMATS AND ATTACHMENTS at URL: http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm. Supplemental information pertaining to Sections G & H of the Sample Contract Format include the following:

1. Section G, "Invoice Submission"

   Invoice Submissions/Contract Financing Request

   Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9. Invoice/financing requests shall be submitted as follows:

   a. An original and two copies to the following designated billing office:

If hand-delivered or delivery Service	If using U.S. Postal Service
Contracting Officer Contracts Management Branch, ORM National Institute of Mental Health 6001 Executive Boulevard Room 6107, MSC 9603 Rockville, Maryland 20852	Contracting Officer Contracts Management Branch, ORM National Institute of Mental Health 6001 Executive Boulevard Room 6107, MSC 9603 Bethesda, Maryland 20892-9603

   Inquiries regarding payment of invoices should be directed to the designated billing office (301) 443-2696.

   b. At a minimum, the Contractor agrees to include the following information on each invoice:

      1. Contractor's name and invoice date
      2. NIMH's Contract number, or other authorization for delivery of property and/or services
      3. Description, cost or price, and quantity of property and/or services actually delivered or rendered
      4. Shipping and payment terms
      5. Other substantiating documentation or information as required by the contract (see paragraph G.3.c, "NIMH Supplemental Billing Instructions" below)
      6. Name where practicable, title, phone number, and complete mailing address of responsible official to whom payment is to be sent

   c. NIMH Supplemental Billing Instructions

1. The contractor agrees to provide, as applicable, a detailed breakdown on each invoice of the following cost categories:

   (a) Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed
   (b) Fringe Benefits - Cite rate and amount
   (c) Overhead - Cite rate and amount
   (d) Materials & Supplies - Include detailed breakdown
   (e) Travel - Identify travelers, dates, destination, purpose of trip, and amount Cite COA, if appropriate
   (f) Consultant Fees - Identify individuals and amounts
   (g) Subcontracts - Attach subcontractor invoice(s). (Should be in same format and detail as required of the Prime Contractor.) Include COA Letter Number if applicable
   (h) Equipment - Cite authorization and amount
   (i) G&A - Cite rate and amount
   (j) Total Cost
   (k) Fee (if applicable)
   (l) Total Cost & Fee

   Monthly invoices must include the cumulative total expended to date, adjusted (as applicable) to show any amounts suspended or disallowed by the Government.

2. The contractor agrees to immediately notify the contracting officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Funds and Limitation of Cost Clauses in the contract.

2. Section G, "Post Award Evaluation of Contractor Performance"

   a. <u>Contractor Performance Evaluations</u>

   Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 41.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually to coincide with the anniversary date of the contract.

   Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty (30) days to review the document and to submit additional information or a rebutting statement. Any disagreement between the parties regarding an evaluation will be referred to an individual one level above the CO, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as a part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address: http://ocm.od.nih.gov/cdmp/cps_contractor.htm

The registration process requires the Contractor to identify an individual that will serve as primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required thirty (30) day time frame.

3. Section H "Human Subjects"

Research involving human subjects shall not be conducted under this contract until the final protocol has been approved by, both your local Internal Review Board (IRB) and the NIMH Data Safety Monitoring Board, written notice of such approval has been provided by the NIMH Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed Optional Form 310 certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, **provided** that it contains the information required by the Optional Form 310.

4. Section H "Options"

Unless the Government exercises its option pursuant to the Option Clause set forth below, the contract will consist only of years 1 through 5. Pursuant to clause 52.217-9 set forth below, the Government may, by unilateral contract modification, require the Contractor to perform additional Years of the Statement of Work. If the Government exercises this option, notice must be given at least 30 days prior to the expiration date of this contract, and the estimated cost of the contract will be increased as set forth in Article B.

Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 10 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.
(c) The total duration of this contract, including the exercise of any options under this clause shall not exceed 10 years.

5. Section H "Required Education In The Protection Of Human Research Participants"

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. The information below is a summary of the NIH Policy Announcement:

The contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

6. Section H "Data And Safety Monitoring In Clinical Trials"

The contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data and Safety Monitoring PLAN shall be established and approved prior to beginning the conduct of the clinical trial.

7. Section H "Task Orders"

a. **Number And Type Of Award(s):** It is anticipated that one award will be made from this solicitation and that the award will be made on/about March 1, 2001. It is anticipated that the award from this solicitation will be a Requirements type contract with a 5-year performance period, one 5-year option to extend the term and that Task Order Procedures will be used.

b. **Definitions:**

Requirements Contract - FAR 16.503 defines a requirements contract as a contract that provides for filling all actual purchase requirements of designated Government activities for supplies or services during a specified contract period, with deliveries or performance to be scheduled by placing orders with the Contractor.

c. **Task Order Procedures:** In providing services under the contract, the following procedures shall apply to the award of task orders (TO's). All work required under the contract shall be authorized through the execution of a bilateral task order. Each TO will obligate the necessary funds to complete the TO and will include the work statement of the task order as an ATTACHMENT. TO's may be issued at any time within the contract period. A Task Order Request (TOR) shall, at a minimum, include a Statement of Work, evaluation factors, specific reporting requirements, deliverables and delivery schedule, the relevant importance of technical and cost factors, and any special instructions.

Budgets shall include direct and indirect costs necessary for performing the proposed task. TO budgets shall generally be limited to a total of 20 pages, including ATTACHMENTS. Within the time allowed for proposal preparation (time allowed for proposal preparation and submission will vary depending on the task), which will be designated in the TOR, the contractor shall submit their budget in response to a TOR, which shall include, but not necessarily be limited to the following information:

(i) A statement of the contractor's clear understanding of the task requirements;
(ii) A statement of technical and managerial resources and expertise the contractor can provide to satisfy the requirement;
(iii) An approach to perform the work;
(iv) The labor category necessary, and the numbers of hours for each labor category necessary, and an explanation of the rationale for determining hours;
(v) Resumes with identification of the actual personnel proposed for the work;
(vi) A schedule of performance identifying major milestones, deliverables and deliver date, and task completion; and

(vii) An itemization of all costs, both direct and indirect, (i.e. personnel, fringe benefits, equipment, travel, supplies, other direct costs, overhead, etc.) necessary to complete the work.

The Government will evaluate the budget and conduct negotiations as necessary. The CO is the only individual authorized to issue a TOR or award a task order under the contract. Unless specifically authorized by the CO, the contractor shall not commence work on a requirement until a modification to the contract has been fully executed.

It is anticipated that task orders will be awarded within 30 calendar days from receipt of TO proposals. Each task order shall, at a minimum, contain the following information:

- Date of order.
- Contract number and task order number sequentially; e.g., N01MH12345 (Task order No. 001, 002, 003, etc).
- Description of services, and estimated cost.
- Performance period.
- Name and address of sponsoring office.
- Name of Contracting Officer's technical representative.
- Place of performance.
- Packaging, packing, and shipping instructions, if any.
- Accounting and appropriation data.
- Pricing Arrangements - Offerors are required to propose hourly ceiling rates for each labor classification in their response to this solicitation, NIMH-01-DS-0002, with cost-reimbursable contract line items proposed for other elements of cost (i.e. fringe benefits, supplies, travel, equipment, other direct costs, indirect costs, fee, etc.). Contracts that are issued to successful offerors will include an advance understanding that will fix hourly rates for each year of the contract. A 3% annual allowance for salary increases will be allowed for each of the subsequent years 2-5. The subsequent negotiation of each TOR issued to the contractor will focus on the number of hours proposed for each labor category and the estimated costs required for all other elements.
- Any other pertinent information.

No protest under FAR Subpart 323.1 is authorized in connection with the issuance or proposed issuance of a task order under the contract except for a protest on the grounds that the order increases the scope, period, or maximum value of the contract. TO awarded under the contract are not subject to the competition requirements of FAR Part 6.

d. **Limitation On Subcontracting:** The restrictions set forth in FAR Clause 52.219-14, Limitation on Subcontracting, will apply to each individual order issued under a task or delivery order contract. The section applicable to this solicitation is FAR Clause 52.219-14(a)(1) and states "Services (except construction). At least 50 percent

of the cost of contract performance incurred for personnel shall be expended for employees of the concern.

e. **Limitation On Period Of Performance Of Orders:** The clause at FAR 52.216-22, Indefinite Quantity, permits orders issued during the effective period of the contract, and not completed within that period, to be completed within the time specified in the order. The time specified in such orders, however, will not extend unreasonably beyond the contract expiration date.

f. **Task Order Contract And Delivery Order Contract Ombudsmen**

a. FAR 16.505(b)(4) requires that each agency designate a task order contract and delivery order contract ombudsman who will be responsible for reviewing complaints from contractors and ensuring that all contractors are afforded a fair opportunity to be considered for orders.

b. The Ombudsman for R&D task and delivery order contracts is Anthony Demsey, Ph.D. Correspondence from awardees on multiple award R&D task and delivery order contracts may be forwarded to the following address:

Anthony Demsey, Ph.D.
Ombudsman for R&D Task and Delivery Order Contracts
c/o Ms. Zaiga Tums, Director, Division of
Acquisition Policy and Evaluation, OAMP
6100 Executive Blvd., Room 6C01
Bethesda, Maryland 20892-7540